

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BAYER AG and BAYER CORPORATION,)
)
 Plaintiffs,)
)
 v.) Civil Action No. 01-148-SLR
)
HOUSEY PHARMACEUTICALS, INC.,)
)
 Defendant.)

Jeffrey B. Bove, Esquire, Mary W. Bourke, Esquire, Gerard M. O'Rourke, Esquire and Elliot C. Mendelson, Esquire of Connolly, Bove, Lodge & Hutz, LLP, Wilmington, Delaware. Counsel for Plaintiffs.

M. Duncan Grant, Esquire, Andrea B. Unterberger, Esquire and Joseph S. Naylor, Esquire of Pepper Hamilton LLP, Wilmington, Delaware. Counsel for Defendant. Of Counsel: Rolf Stadheim, Esquire, Joseph A. Gear, Esquire and George C. Summerfield, Esquire of Stadheim & Gear, Ltd., Chicago, Illinois.

MEMORANDUM OPINION

Dated: October 17, 2001
Wilmington, Delaware

ROBINSON, Chief Judge

I. INTRODUCTION

Plaintiffs Bayer AG and Bayer Corporation filed this action on March 6, 2001 seeking a declaratory judgment that four patents assigned to defendant Housey Pharmaceuticals, Inc. are invalid, unenforceable and not infringed.¹ (D.I. 1) Defendant has filed a counterclaim of infringement. (D.I. 5) The court has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a) and 2201(a). Currently before the court are plaintiffs' motion to dismiss defendant's infringement claim under 35 U.S.C. § 271(g) (D.I. 14) and defendant's motion to dismiss plaintiffs' claim of patent misuse. (D.I. 6) For the following reasons, the court shall grant plaintiffs' motion and deny defendant's motion.

II. BACKGROUND

The ICT patents, each entitled, "Method of Screening for Protein Inhibitors and Activators," generally relate to research methods used by pharmaceutical companies for discovering drugs. (D.I. 1) The patented methods enable companies to screen substances for active compounds that

¹Defendant Housey Pharmaceuticals, Inc. recently changed its name from ICT Pharmaceuticals, Inc. (D.I. 38) The patents in suit are United States Patent Nos. 4,980,281, 5,266,464, 5,688,655 and 5,877,007 (collectively, the "ICT patents").

indicate a potential for development as pharmaceuticals.

(Id.) Illustrative of the "screening method" claims allegedly infringed by plaintiffs is claim 1 of United States Patent No. 4,980,281, which reads:

1. A method of determining whether a substance is an inhibitor or activator of a protein whose production by a cell evokes a responsive change in a phenotypic characteristic other than the level of said protein in said cell per se, which comprises:

(a) providing a first cell line which produces said protein and exhibits said phenotypic response to the protein;

(b) providing a second cell line which produces the protein at a lower level than the first cell line, or does not produce[] the protein at all, and which exhibits said phenotypic response to the protein to a lesser degree or not at all;

(c) incubating the substance with the first and second cell lines; and

(d) comparing the phenotypic response of the first cell line to the substance with the phenotypic response of the second cell line to the substance.

Defendant alleges that plaintiffs infringe the ICT patents under 35 U.S.C. § 271(g) when they: (1) sell in the United States a drug that was determined to be an inhibitor or activator of a target protein using the patented methods; and (2) import into or use in the United States knowledge and information reflecting the identification or characterization of a drug acquired from using the patented methods. (D.I. 22 at 5)

Plaintiffs contend that defendant is misusing the ICT patents, and has alleged the following:

13. [Defendant] has demanded that [plaintiffs] agree to a license of the ICT patents. The terms of the license offered by [defendant] would require [plaintiffs] to pay substantial royalties based on [plaintiffs'] total research and development budget and/or total sales revenues for any commercialized products "in which the patented technology was utilized in the research and development leading to the drug." The requested royalty payments are to extend through the life of [plaintiffs'] patent(s) on the commercialized drug products.

24. On information and belief, [defendant] has licensed the ICT patents with terms that require the licensees to pay royalties on compounds allegedly identified or selected for further development or commercialization by use of the ICT patented assay methods even though there is not a single claim in any of the ICT patents that is directed to such compounds.

25. On information and belief, [defendant] has also licensed the ICT patents with terms as set forth in paragraph 13 above, knowing that the claims do not cover such compounds.

26. On information and belief, [defendant] has also licensed the ICT patents with terms that require the licensees to continue to pay royalties on compounds identified or selected for further development by use of the assay method claimed in the ICT patents after expiration of the ICT patents.

27. [Defendant] has engaged in activities which constitute misuse of the ICT patents, rendering the ICT patents unenforceable.

(D.I. 1 at 4-6)

III. STANDARD OF REVIEW

In analyzing a motion to dismiss pursuant to Rule 12(b)(6), the court must accept as true all material allegations of the complaint and it must construe the complaint in favor of the plaintiff. See Trump Hotels & Casino Resorts, Inc. v. Mirage Resorts, Inc., 140 F.3d 478, 483 (3d Cir. 1998). "A complaint should be dismissed only if, after accepting as true all of the facts alleged in the complaint, and drawing all reasonable inferences in the plaintiff's favor, no relief could be granted under any set of facts consistent with the allegations of the complaint." Id. Claims may be dismissed pursuant to a Rule 12(b)(6) motion only if the plaintiff cannot demonstrate any set of facts that would entitle him to relief. See Conley v. Gibson, 355 U.S. 41, 45-46 (1957). The moving party has the burden of persuasion. See Kehr Packages, Inc. v. Fidelcor, Inc., 926 F.2d 1406, 1409 (3d Cir. 1991).

IV. DISCUSSION

A. Defendant's Infringement Claim under 35 U.S.C. § 271(g) Is Dismissed as a Matter of Law

Plaintiffs argue that the court should dismiss defendant's claim of infringement under 35 U.S.C. § 271(g) because the statute is not applicable to patents claiming research methods. Section 271(g) provides, in pertinent part:

Whoever without authority imports into the United States or offers to sell, sells or uses within the United States **a product which is made by a process patented in the United States** shall be liable as an infringer . . . A product which is made by a patented process will, for purposes of this title, not be considered to be so made after –

- (1) it is materially changed by subsequent processes, or
- (2) it becomes a trivial and nonessential component of another product.

35 U.S.C. § 271(g) (emphasis added).

Upon a plain reading of the statute, the court finds that Section 271(g) addresses only products derived from patented **manufacturing processes**, i.e., methods of actually making or creating a product as opposed to methods of gathering information about, or identifying, a substance worthy of further development. To date, the Federal Circuit has not expanded the application of Section 271(g) beyond methods of manufacture. See, e.g., Bio-technology Gen. Corp. v. Genentech, Inc., 80 F.3d 1553, 1560-61 (Fed. Cir. 1996) (holding that importation of hormone made by patented recombinant DNA techniques infringes under § 271(g)); Eli

Lilly & Co. v. Am. Cyanimid Co., 82 F.3d 1568, 1571-73 (Fed. Cir. 1996) (holding that importation of antibiotic does not infringe patent claiming method of making intermediate compound where compound was "materially changed"); Mars, Inc. v. Nippon Conlux Kabushiki-Kaisha, 855 F. Supp. 670, 672 (D. Del. 1993), aff'd, 58 F.3d 616 (Fed. Cir. 1995) (holding that patent describing process by which electronic coin changer in vending machine analyzes coins is not manufacturing process and, therefore, not covered by § 271(g)).²

In the case at bar, the asserted method claims of the ICT patents describe processes for recognizing substances with the potential for development into pharmaceuticals. These processes of identification and generation of data are not steps in the manufacture of final drug products. Thus, § 271(g) is not applicable to the processes claimed in the ICT patents and defendant's infringement claim under Section 271(g) is dismissed.

B. Plaintiffs Have Sufficiently Stated a Claim of Patent Misuse

²The court also finds plaintiffs' policy arguments persuasive. If § 271(g) were applicable to patents claiming screening methods or methods of use, any products subjected to those methods in foreign countries would infringe those patents upon importation to the United States. Such sweeping liability is beyond the scope of the statute.

Defendant contends that plaintiffs have failed to state a claim of patent misuse. "Patent misuse relates primarily to a patentee's actions that affect competition in unpatented goods or that otherwise extend the economic effect beyond the scope of the patent grant." C.R. Bard, Inc. v. M3 Sys., Inc., 157 F.3d 1340, 1372 (Fed. Cir. 1998). Arrangements in which a patentee effectively extends the term of its patent by requiring post-expiration royalties constitute per se patent misuse. See Virginia Panel Corp. v. MAC Panel Co., 133 F.3d 860, 869 (Fed. Cir. 1997) (citing Brulotte v. Thys. Co., 379 U.S. 29, 33 (1964)). Certain practices that do not equal per se patent misuse may constitute misuse if a court determines that such practices do not reasonably relate to the subject matter within the scope of the patent claims.³ If "the

³Congress has excluded certain practices from constituting patent misuse in 35 U.S.C. § 271(d), which provides:

No patent owner otherwise entitled to relief for infringement or contributory infringement of a patent shall be denied relief or deemed guilty of misuse or illegal extension of the patent right by reason of his having done one or more of the following: (1) derived revenue from acts which if performed by another without his consent would constitute contributory infringement of the patent; (2) licensed or authorized another to perform acts which if performed without his consent would constitute contributory infringement of the patent; (3) sought to enforce his patent rights against infringement or contributory

practice has the effect of extending the patentee's statutory rights and does so with an anti-competitive effect, . . . the finder of fact must decide whether the questioned practice imposes an unreasonable restraint on competition . . ."

Virginia Panel, 133 F.3d at 869.

Although defendant has offered explanations of its licensing arrangements in its briefing and during oral argument, at this juncture, the court is limited to what appears on the face of the pleadings. Because plaintiffs' complaint contains allegations that, if proved to be true, conceivably could persuade a rational factfinder that defendant misused the ICT patents, the court finds that plaintiffs have sufficiently stated a claim of patent misuse.

V. CONCLUSION

For the reasons stated, plaintiffs' motion to dismiss defendant's infringement claim under 35 U.S.C. § 271(g) is

infringement; (4) refused to license or use any rights to the patent; or (5) conditioned the license of any rights to the patent or the sale of the patented product on the acquisition of a license to rights in another patent or purchase of a separate product, unless, in view of the circumstances, the patent owner has market power in the relevant market for the patent or patented product on which the license or sale is conditioned.

granted and defendant's motion to dismiss plaintiffs' claim of patent misuse is denied. An appropriate order shall issue.

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O R D E R

At Wilmington, this 17th day of October, 2001, consistent with the memorandum opinion issued this same day;

IT IS ORDERED that:

1. Plaintiffs' motion to dismiss defendant's infringement claim under 35 U.S.C. § 271(g) (D.I. 14) is granted.

2. Defendant's motion to dismiss plaintiffs' claim of patent misuse (D.I. 6) is denied.

United States District Judge